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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,695	09/25/2003	Wayne A. Jensen	DI-9-1	8741

26949 7590 03/05/2008

HESKA CORPORATION
LEGAL DEPARTMENT
3760 ROCKY MOUNTAIN AVE
LOVELAND, CO 80538

EXAMINER
HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
03/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gordons@heska.com
sternri@heska.com
flandej@heska.com

Office Action Summary	Application No.	Applicant(s)	
	10/670,695	JENSEN ET AL.	
	Examiner	Art Unit	
	LOUISE HUMPHREY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-113,115-130 and 132-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108-113,115-130 and 132-146* is/are rejected.

7)☒ Claim(s) *108* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the argument and amendment filed on 30 November 2007. Claims 1-107, 114 and 131 have been cancelled. Claims 108-113, 115-130 and 132-146 are pending and currently examined.

Claim Objections

The objection to claim 108 is **maintained** in response to Applicant's amendment. Applicants added a limitation reciting the abbreviated name "FHV" without first identifying the full name, feline herpes virus. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 108-113, 115-130 and 132-146 under 35 U.S.C. §103(a) as being obvious over Maeda *et al.* (1997) in view of Prud'homme *et al.* (1997) and Scott *et al.* (1999, IDS No. C14) **is maintained**.

The instant claims are directed to a method comprising contacting a biological specimen with a recombinant protein comprising at least 300 contiguous amino acids from SEQ ID NO:18, SEQ ID NO:20 or SEQ ID NO:22 under conditions suitable for

formation of a complex with an antibody, detecting the protein-antibody complex, and in the absence of the complex, vaccinating the animal against herpesvirus.

Maeda *et al.* disclose that glycoprotein (gC) as a subunit antigens in vaccine immunity for FHV-1 infection in cats and that monoclonal antibodies reacting with the gC can evaluate the gC antigen in vaccines (page 108, last ¶). Secondly, Maeda *et al.* disclose the nucleotide and amino acid sequence of a recombinant FHV type 1 (FHV 1) gC protein (page 107) expressed in COS cells (page 106), which aligns with the instantly claimed SEQ ID NO:22 and differs from SEQ ID NO: 18 and 20 by one amino acid, from valine in SEQ ID NO: 18 or 20 to glycine, which is *prima facie* obvious since the minor change in chemical configuration or design of molecule discovered or made by applicants is *de minimis*, since there is no evidence that the change from valine to glycine of epitope is essential for immunogenic activity, and since applicants have not explained practical advantages of any differences in the structure between claimed sequence and prior art. See *Ex Parte Anderson* 30 USPQ2d 1866 (Bd. Pat. App. & Int. 1993).

Maeda *et al.* do not disclose detection of antibody:protein complex prior to vaccination.

Prud'homme *et al.* disclose a recombinant herpes virus glycoprotein antigen, gp50 used in a competitive ELISA for detection in animal sera of antibodies of pseudorabies virus (PRV), an alphaherpesvirus (page 278, Materials and Methods). Prud'homme *et al.* further disclose that ELISAs, either as indirect or competitive formats,

have been used to discriminate between naturally infected and vaccinated animals (page 287, 1st column, line 10-14).

Prud'homme *et al.* do not explicitly suggest vaccination when not detecting the antibody-protein complex.

Scott *et al.* disclose a method to evaluate duration of immunity in cats vaccinated with a vaccine of feline panleukopenia virus (FPV), feline herpesvirus (FHV), and feline calcivirus (FCV) and specifically recommend that cats be revaccinated against FPV-FHV-FCV (Abstract). Specifically, antibody titers against FPV, FHV, and FCV in the sera samples of the vaccinated and unvaccinated contact control cats are measured. See page 653, 2nd column, last paragraph and Figure 1.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify FHV-1 gC vaccination method disclosed by Maeda *et al.* such that the same vaccine antigen is used in the detection of antibody-protein complex, as taught by Prud'homme *et al.*, such that the presence or absence of the antibody-protein complex is employed in the method to evaluate the immune status and to determine whether to vaccinate against FPV-FHV-FCV as suggested by Scott *et al.* One having ordinary skill in the art would have been motivated to do so to more accurately assess the immune status of the animal and identify the animals in need of the FHV, FCV or FPV vaccine with this specific recombinant antigen since Maeda *et al.* explicitly suggest the application of the glycoprotein C as a subunit antigen in vaccine immunity for FHV-1 infection in cats (p. 108, last ¶). There would have been reasonable expectation of success given that a herpes virus glycoprotein is routinely used by one

skilled in the art for the detection of antibody:antigen complex to evaluate immune status in animals, as taught by Prud'homme *et al*. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed on 30 November 2007 have been fully considered but they are not persuasive.

Applicants argue that neither the Scott reference nor the Maeda reference provides a nexus between detecting protective antibodies in sera and the gC protein of FHV. However, Applicants left out the Prud'homme reference in the argument. The instant claims are directed to a method comprising contacting a biological specimen with a recombinant gC protein comprising at least 300 contiguous amino acids from SEQ ID NO:18, SEQ ID NO:20 or SEQ ID NO:22, detecting the protein-antibody complex, and in the absence of the complex, vaccinating the animal against herpesvirus. The Maeda reference discloses vaccinating the animals against herpesvirus and all the recombinant gC antigens comprising at least 300 contiguous amino acids from SEQ ID NO:18, SEQ ID NO:20 or SEQ ID NO:22. The Prud'homme reference describes detecting the antigen:antibody complex using an alphaherpesvirus glycoprotein. Therefore, every claim limitation is met by the Maeda and the Prud'homme references. FHV is an alphaherpesvirus. Thus, the combination of the Maeda reference and the Prud'homme reference provides the nexus between detecting

antigen-specific antibodies in a biological specimen and the vaccination with gC protein of FHV.

Applicants argue that Scott *et al.* disclose determining anti-FHV antibody titer by virus neutralization assays that utilize whole viruses, not the claimed recombinant antigen. However, this argument mischaracterizes the rejection because Scott *et al.* was proffered for teaching the motivation or suggestion to modify the Maeda method by including an additional step of detecting antigen:antibody complex as taught by Prud'homme *et al.*, before vaccination against FHV, as taught by Scott *et al.* Scott *et al.* disclose the rationale of evaluating the immune status, which determines the necessity of vaccination, before vaccinating the animals. The step of determining anti-FHV antibody by a recombinant glycoprotein antigen is taught by Prud'homme *et al.* Thus, the obviousness of the combination does not hinge on whether Scott *et al.* suggest using a recombinant antigen. Rather, the motivation to combine the references was to use the Prud'homme reference's antigen:antibody to detect FHV antibody in a vaccination method using a recombinant gC antigen as taught by Maeda *et al.*, so that the antigen:antibody detection determines the amount of antibody titer left in the animal body and thereby determines whether the animal needs the vaccination, as taught by Scott *et al.* Thus, the combination of Maeda *et al.*, Prud'homme *et al.* and Scott *et al.* is properly motivated.

Applicants further argue against the Maeda reference, specifically, against the phrase that the results "might contribute for the evaluation of the gC protein as one of the most important" antigens in immunity. Applicants assert that this phrase should be

interpreted as nothing more than a suggestion by Maeda *et al.* to further explore the role of the gC protein in immunity to infection and that viral protein other than gC may be responsible for protection from infection. However Applicants believe the sentences should read, Maeda *et al.* explicitly disclose the claimed recombinant antigen and the claimed method of vaccination with gC protein. Applicants further cited the Horimoto reference as evidence to show that there is no correlation between *in vitro* antibody neutralization and *in vivo* protection. However, the evidence in the Horimoto reference is not relevant to the instant invention because the lack of in vitro and in vivo correlation of antibody response is detected in a 107 kDa glycoprotein, which is different from the claimed gC antigens taught by the Maeda reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/L. H./
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648